

Key Take Home Messages:

- Xospata significantly prolonged OS and EFS compared with salvage chemotherapy in patients with R/R *FLT3*mut+ AML in Asia
- When adjusted for treatment exposure, safety/tolerability was favorable for Xospata compared with salvage chemotherapy
- Results of the COMMODORE trial further validate and affirm the clinical efficacy and safety data from the ADMIRAL trial, reinforcing the significant benefit of Xospata in R/R *FLT3*mut+ AML^{2,3}



References:

1. Wang, J., Jiang, B., Li, J. et al. Phase 3 study of gilteritinib versus salvage chemotherapy in predominantly Asian patients with relapsed/refractory FLT3-mutated acute myeloid leukemia. *Leukemia* 38, 2410–2418 (2024). <https://doi.org/10.1038/s41375-024-02382-9>
2. Perl AE, Martinelli G, Cortes JE, et al. Gilteritinib or chemotherapy for relapsed or refractory FLT3-mutated AML. *N Engl J Med* 2019; 381(18): 1728-1740.
3. XOSPATA prescribing information (India-Version PI /India/Ver3.0/Jan 2023).

Additional information available on request

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Scan for Xospata PI



XOSPATA
gilteritinib





XOSPATATM

ADVANTAGE

COMMODORE¹

Xospata or Chemotherapy for Relapsed or Refractory FLT3-Mutated AML
A Phase 3, Randomized, Multicenter, Open-Label Trial In Asia



Patients in Asia^a with R/R *FLT3*^{mut}+ AML

1:1 randomization^b

n=116

Xospata
120 mg orally per day
Over continuous 28-day cycles

n=118

Salvage Chemotherapy^c
• Low-dose cytarabine
Over continuous 28-day cycles
• Mitoxantrone, etoposide, and intermediate-dose cytarabine
• Fludarabine, high-dose cytarabine, and G-CSF
For up to two cycles depending on response and safety assessment

Key eligible criteria: ECOG score ≤2
Patients with acute promyelocytic leukemia, BCR-ABL-positive leukemia, clinically active central nervous system disease, or secondary AML were excluded

Commodore Trial Endpoints:

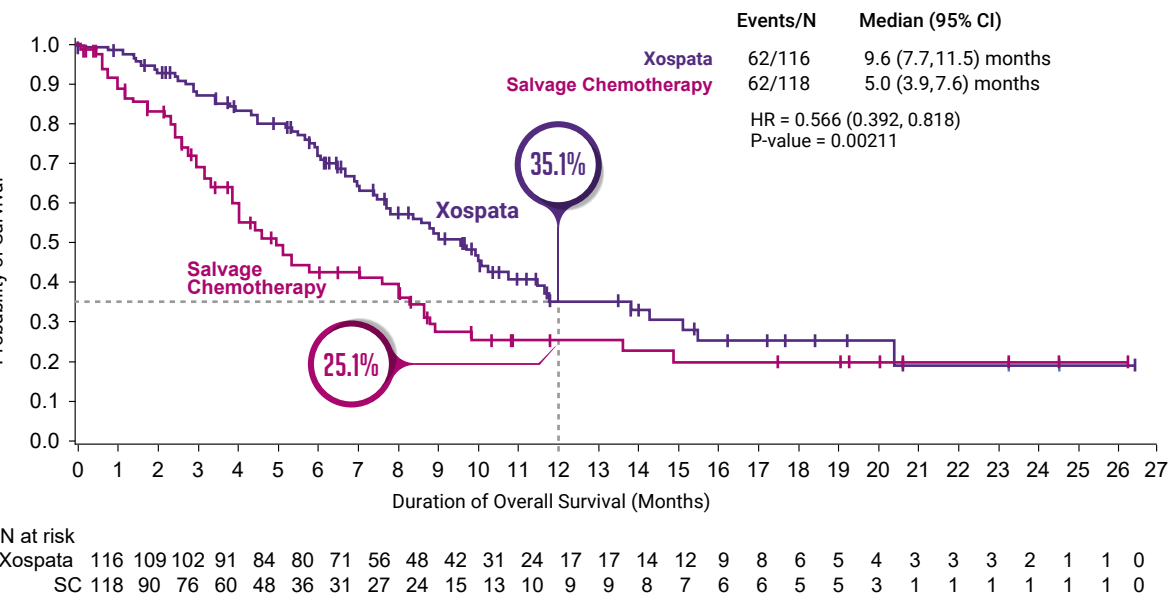
Primary Endpoint:
• Overall Survival (OS)

Secondary Endpoints:

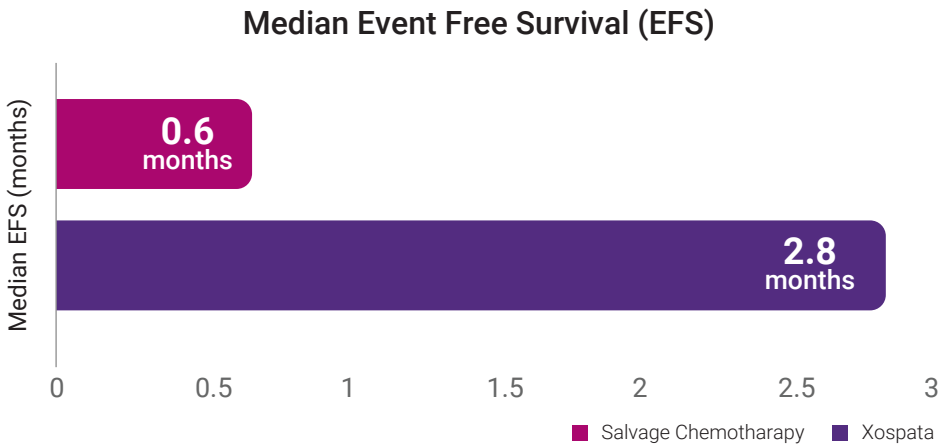
- Event-free survival (EFS)
- Complete remission (CR)
- Duration of remission
- Composite complete remission (CRc*)
- Safety/tolerability

* CRc: combined CR, CR with incomplete platelet recovery, and CR with incomplete hematologic recovery
a. Patients in China, Russia, Singapore, Thailand, and Malaysia. b. Randomization was stratified by response to first-line therapy and preselected salvage chemotherapy.
c. Investigator-preselected prior to randomization • G-CSF: granulocyte colony-stimulating factor

Overall survival was significantly longer in the Xospata group vs salvage chemotherapy group



Patients treated with Xospata had significantly longer event-free survival than those with salvage chemotherapy



CR and CRc rates with Xospata and Salvage Chemotherapy

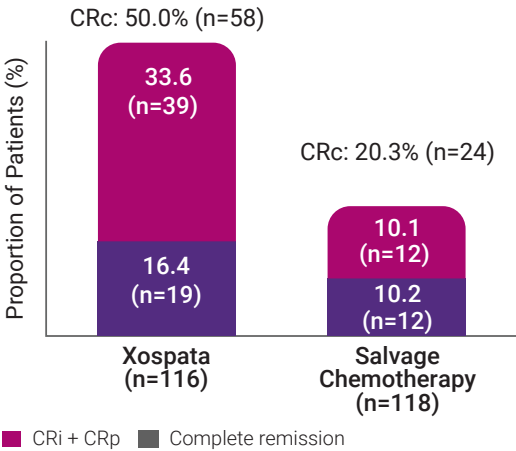
The proportion of patients achieving CR on Xospata compared with salvage chemotherapy appeared higher, however, were not significantly different

➤ Treatment difference: 6.2% P=0.17690

Rates of CRc were significantly higher

➤ Treatment difference: 29.7% P<0.00001

^ not significantly different
CR, complete remission; CRc, composite complete remission
CRi, complete remission with incomplete hematologic recovery;
CRp, complete remission with incomplete platelet recovery
CRc= CR + CRp + CRi



Grade ≥3 adverse events were lower with Xospata vs salvage chemotherapy (treatment-adjusted results)

- When adjusted for treatment exposure, the rates of grade ≥3 and serious adverse events were lower with Xospata versus salvage chemotherapy
- Adverse events leading to death occurred in 22 (19.5%) patients receiving Xospata and 15 (14.4%) patients receiving salvage chemotherapy

